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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/582,863	07/06/2000	David Gustafsson	3525-86	4411
23117	7590	11/10/2004	EXAMINER	
NIXON & VANDERHYE, PC 1100 N GLEBE ROAD 8TH FLOOR ARLINGTON, VA 22201-4714			KAM, CHIH MIN	
			ART UNIT	PAPER NUMBER
			1653	

DATE MAILED: 11/10/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

## Application No.

09/582,863

## Applicant(s)

GUSTAFSSON, DAVID

## Examiner

Chih-Min Kam

## Art Unit

1653

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 29 September 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 20,22-43,46-49 and 51-57 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 20,22-43,46-49 and 51-57 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413)          |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. <u>20041103</u> .                                    |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____.  | 6) <input type="checkbox"/> Other: _____.                                   |

### **DETAILED ACTION**

1. The finality of previous Office Action is withdrawn due to a new ground of rejection.

#### ***Status of the Claims***

2. Claims 20, 22-43, 46-49 and 51-57 are pending.

Applicants' amendment filed on September 29, 2004 is acknowledged, and applicants' response has been fully considered. Claims 20 and 28-32 have been amended, and claims 21, 44, 45 and 50 have been cancelled. Thus, claims 20, 22-43, 46-49 and 51-57 are examined. A proposed Examiner's Amendment was faxed to the applicant on October 22, 2004 (see attached Interview Summary), however, it was not accepted.

#### **Objection Withdrawn**

3. The previous objection of claims 21, 24-28, 30, 36-40 and 44-57 is withdrawn in view of applicants' amendment to the claims and applicants' cancellation of the claim in the amendment filed September 29, 2004.

#### **Rejection Withdrawn**

#### ***Claim Rejections - 35 USC § 102***

4. The previous rejection of claims 20, 22, 23, 29 and 31-35, under 35 U.S.C. 102(e) as being anticipated by Lam *et al.* (U.S. Patent 6,602,871), is withdrawn in view of applicants' amendment to the claims and applicants' response at page 10 in the amendment filed September 29, 2004.

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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4. Claims 20, 22-43, 46-49 and 51-57 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

5. Claims 20, 22-43, 46-49 and 51-57 are indefinite because of the use of the term “a pharmaceutically acceptable derivative thereof”. The term cited renders the claim indefinite, it is not clear what structure the derivatives has, how different the derivative is from the parent compound, and whether the derivative is a prodrug of the thrombin inhibitor. Although the specification indicates the derivatives “include” salts and solvates, as well as the derivatives that have the same biological function or activity as the thrombin inhibitors, but do not include prodrugs of that thrombin inhibitor (page 7, last paragraph), the specification does not specifically define the term, thus it is not clear what compounds the derivatives are.

Furthermore, the claim does not exclude the prodrug of thrombin inhibitor. Claims 22-30, 33-40, 42, 43, 46-49 and 51-57 are included in this rejection for being dependent on a rejected claim and not correcting the deficiency of the claim from which they depend.

6. Claim 22 recites the limitation "separate ...use" in line 2. There is insufficient antecedent basis for this limitation in the claim, because the independent claim, claim 20 recites the formulations (a) and (b) are suitable for administration “in conjunction with” each other.

7. Claim 31 is indefinite because of the use of the term “(or a pharmaceutically acceptable derivative thereof)”, it is not clear whether the limitation in the parentheses (..) is part of the claimed invention.

### ***Conclusion***

8. No claims are allowed.

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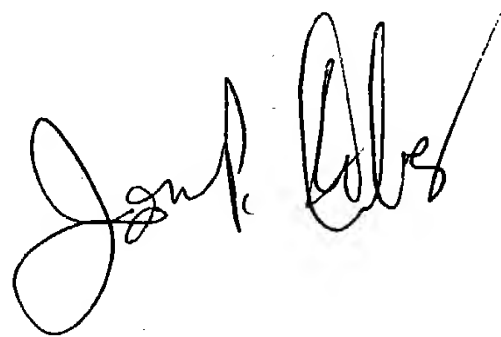
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (571) 272-0948. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached at 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Chih-Min Kam, Ph. D. *CMK*  
Patent Examiner

CMK  
November 3, 2004

  
**JON WEBER**  
**SUPERVISORY PATENT EXAMINER**